

# Introduction

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Since its inception in 1994, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has embodied the orthodox view that enforcing strong intellectual property rights (IPRs) is necessary to solve problems of trade and development. The Doha Declaration of 2001 offered short periods of special dispensation, especially to least developed countries, and proclaimed one goal to be the promotion of “access to medicines for all.” Nonetheless, it is important to recognize that the Declaration did not disturb the orthodox view of strong IPRs reflected in TRIPS. The editors of this collection reject this view and the traditional development theory that underlies it, particularly the theory’s binary model of the world as comprising developed countries and all the rest who must follow the IPR-laden path to development. The editors share the conviction that the TRIPS regime of strong IPRs is increasingly out of phase with the shifting geopolitical dynamics of multilateralism in international relations, a multilateralism in which human rights has become a progressively more influential factor in shaping trade and development policy.

The editors of this collection ask: How can TRIPS mature further into an institution that supports a view of economic development which incorporates the ensemble of human rights now seen as encompassing a more comprehensive set of collective interests that includes public health, environment, and nutrition? In particular how can this twenty-first century congregation of human rights provide a pragmatic ethic for accomplishing a rapport with IPRs in the new landscape of development policy?

Addressing such questions, the chapters in the first part of the collection shed new light on recent deployments of human rights ethics, international treaty obligations, and domestic law that have had success in reshaping IPRs, deployments made in developing countries and the BRIC (Brazil, Russia, India and China) group. The chapters in the second part make new proposals and recommendations for the further use of human rights and related ethics to resolve conflict over IPRs in ways that can benefit less-developed countries.

Such conflict was inevitable, especially between patent rights, given

their continuing expansion in the pharmaceutical and biotechnology sectors, and human rights, which now comprise a wider array of collective interests. The conflict between patent rights and human rights is widely understood as expressing a particularly difficult form of the familiar tension between efficiency and dispersion, between encouraging innovation and promoting fair distribution.<sup>1</sup> This dominant view of the conflict bears scrutiny. Why? Because the economic theory supporting patent rights as the engine of research and development is not well supported. In consequence, it cannot be taken for granted that the moral virtue of wider distribution of patented goods, especially pharmacological products, exacts a high price on research and development.

## WHAT IS THE CONFLICT BETWEEN PATENT RIGHTS AND HUMAN RIGHTS?

The rights conflict in mainstream policy debate persists with great force because both sides are supported by international treaties as well as domestic law, whether constitutional or legislative in form. Moreover, on both sides, the rights are doubly justified, first, by economic arguments and second, by natural rights claims. Patent rights are understood as the economic incentive necessary to encourage innovation and, with it, economic growth; they are also seen as a particularly attractive form of natural right, one that not only takes up the Lockean call to protect the fruits of one's labor but also conjures the Romantic ideal of nurturing the individual Imagination.<sup>2</sup> At the same time, human rights are seen as encompassing natural rights to food and shelter, and to health and medicine, rights to some extent reflected in the Lockean proviso of leaving "enough and as good" for those who follow; moreover, the economic logics of efficiency are literally dependent on the scale and scope of distribution in both the short and long terms, in regard to both the microeconomic sense that allocative efficiency is by definition a function of distribution and, second, in the macroeconomic sense that both the consumption and production functions driving economic growth expand in populations that live in conditions of better health and nutrition.

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<sup>1</sup> And, even more fundamentally, the complex relationship between liberty and equality.

<sup>2</sup> Supporting these forces is the anxious neo-mercantilist insistence, certainly in the United States, that patent (as well as copyright and trade secret) protection must be maximized because it represents the last competitive advantage in global markets.

Yet, the conflict as it has played out in mainstream debate over trade and development does not reflect these double justifications. Instead, patent rights have typically been justified in economic terms while human rights have largely been asserted as natural rights that should curb if not trump patent rights despite their assertedly ill-effects on technological innovation and, with it, on economic growth. In the context of development, global mappings of trade have long shown hemispheric profiles of import and export, whether north–south or east–west. But the emergence of the BRIC countries and their predecessors, including Taiwan and Korea, has not only complicated hemispheric profiles of trade and development but also injected new dynamics into the TRIPS regime of strong patent rights because of those countries’ dual interests as both IP importers and exporters, as well as their mercantilist fiscal and trade policies.<sup>3</sup> This complexity amplifies the importance of interrogating the orthodox justification for strong patent rights as the incentive necessary for vigorous innovation and, with it, economic growth and development.

The orthodox scholarly conception of patents as the instrument of economic growth is supported by the intuitively attractive economic tenet that patents provide the financial incentive needed for inventors and their investors to engage in research and development. The assumption is that all society benefits from the economic growth that results. In economic terms, without the incentive of patent rights, new ideas and their embodiments are too quickly and too easily copied, imitated, and reproduced. Inventors and their investors will not profit enough to undertake the risky enterprise of research and development. In the orthodox view that supports TRIPS, patents are justified in economic terms by the need to privatize positive externalities, by the market failure of unfettered competition.

In this light, many scholars and policy makers call for expanded patent protection on the logic that more is better, that maximizing the means of patent protection maximizes the ends of promoting economic progress. This maximalist logic makes intuitive sense insofar as the greater private profits stemming from stronger patent protection are understood as spurring more innovation and, with it, the greater public benefits of increased economic growth.

Although the economic incentive rationale and its maximalist logic are intuitively attractive, the fact is that they simply do not hold together. Indeed, economists and policy analysts have recognized deep problems

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<sup>3</sup> Of course, the TRIPS Agreement can itself be understood as neo-mercantilist, with IP rather than gold as the marker of wealth and IPRs rather than tariffs as the regulating mechanism.

since the nineteenth century.<sup>4</sup> The problems are both theoretical<sup>5</sup> and empirical. The empirical research is particularly arresting: Despite more than 50 years of studies, economists have not produced empirical evidence to support the claim that the economic benefits of patents are superior to those of patent-free [or open] competition in encouraging innovation or advancing economic growth. In sum, the theoretical critiques and empirical results conclude that increasing the private benefits of patents to inventors and investors tells us nothing about their effects on the public good, particularly on economic growth.

The result is an analytical stalemate that the orthodox view does not acknowledge, a stalemate because both patent protection and patent-free

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<sup>4</sup> See, e.g., WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 9–10, 294–333 (Cambridge, MA: Harvard University Press 2003). References for the analysis that follows as well as further discussion can be found in Rudolph J.R. Peritz, *Competition Within Intellectual Property Regimes – The Instance of Patent Rights*, in *INTELLECTUAL PROPERTY AND COMPETITION LAW: NEW FRONTIERS*, Ariel Ezrahi & Steven D. Anderman, eds (Oxford, UK: OUP 2011); Rudolph J.R. Peritz, *Essay Thinking about Economic Progress: Arrow and Schumpeter in Time and Space*, in *TECHNOLOGY AND COMPETITION: CONTRIBUTIONS IN HONOUR OF HANNS ULLRICH*, Josef Drexl, ed. (Bruxelles: Larcier Pub. 2009); Rudolph J.R. Peritz, *Freedom to Experiment: Toward a Concept of Inventor Welfare*, 90 *J. PATENT & TRADEMARK OFFICE SOCIETY* 245 (2008), available at SSRN URL <http://ssrn.com/author=75649>. For discussion of the European debates, see Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 *J. ECON. HIST.* 1 (1950), analyzed in Rudolph J.R. Peritz, *Patents and Progress: The Economics of Patent Monopoly and Free Access*, in *INTELLECTUAL PROPERTY RIGHTS: DOES ONE SIZE FIT ALL?*, Annette Kur, ed. (Cheltenham: Edward Elgar Pub. 2009).

<sup>5</sup> The theoretical critiques begin with the general proposition that there is no logical basis for assuming that increasing the means increases the wished-for ends. As a matter of logic, stronger patents do not necessarily lead to more public benefits. Means–ends relationships are determined not by abstract logic but by empirical and moral inquiry. Simply conflating them is a logical category error. Then there are the more focused economic criticisms of equating patent protection with economic growth, the criticism for instance that incentive theory does not take into account opportunity costs and thus overstates the public benefits of patent protection. Why? Because it ignores the lost benefits of alternative investments, public benefits that would have resulted from investment in, for example, more production or more unpatentable research and development. Further, patent rights produce the social cost of monopoly profits that diminishes dispersion of the patented inventions to both consumers and later inventors. As well, proliferating patent rights produce increasing transaction costs of technology transfer, costs encapsulated in the concept of anti-commons. In sum, there is no theoretical basis for claiming that as a general matter the social benefits of a patent regime justify its considerable social costs.

competition contribute to economic growth but to indeterminable degrees. In short, the TRIPS commitment to strong patent rights as the necessary foundation for the success of a global trade and development regime lacks economic support.

Several alternatives to the incentive theory of patents have emerged in the literature, alternatives ranging from tinkering within the strong rights regime to rejecting the entire formulation.<sup>6</sup> Despite disagreements, they all stem from the same recognition that an economic logic of incentive theory cannot provide a technical solution to patent policy questions of economic progress. It turns out that patent policy makers can do no better than “muddle through” hard choices based on economically informed estimates and normative judgments about social welfare, however conceived.

In this economic light, there is no fundamental conflict between patent rights and human rights. There are only overlapping questions whose resolution should take into account the economic and moral dimensions of social welfare. Thus human rights activists need not argue that the economic costs of declining innovation are worth the moral virtue of wider dissemination because, as a general matter, no one can determine whether innovation would decline or, if it would, whether the decline would produce economic costs or benefits.

The policy analysis that emerges, then, calls for identifying and weighing the economic and moral dimensions of social welfare in the particular circumstances. Here, the circumstances involve pharmaceutical and biotechnology patent rights, and human rights to health, nutrition, and medicine. As for the patent rights, a landmark study of data from interviews of research and development directors in the United States supports a claim that patents provide significant incentive to the pharmaceutical industry, apparently because research and development is costly and imitation is cheap in that sector.<sup>7</sup> Still, these findings should be understood for what they are—the importance of patents for private profitability in specific

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<sup>6</sup> For discussion, see Rudolph J.R. Peritz *Patents and Progress: The Economics of Patent Monopoly and Free access*, in *INTELLECTUAL PROPERTY RIGHTS: DOES ONE SIZE FIT ALL?*, Annette Kur, ed. (Cheltenham: Edward Elgar Pub. 2009). Of course, tinkering could be extensive, whether by intra-regime measures such as constricting patent scope, expanding the misuse doctrine, or raising the standard of non-obviousness, or by extra-regime measures such as stricter enforcement of antitrust doctrines limiting the opportunities for abuse by dominant firms, patent pools, or holders of patents in industry-standard inventions.

<sup>7</sup> Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson, Sidney G. Winter, Richard Gilbert, Zvi Griliches, *Appropriating the Returns from Industrial Research and Development*, *BROOKINGS PAPERS ON ECONOMIC ACTIVITY* 783–831(1987) (100-industry survey).

contexts and for specific markets, a finding which has nothing to say about social welfare, defined in terms of economic growth.

However, in these particular circumstances, the impact on social welfare calls for additional analysis. For if social welfare is defined more broadly, then private gains to pharma and biotech companies should not be ignored simply because there is no basis for estimating their impact on economic growth. For example, development of new cancer treatment or virus vaccine advances social welfare regardless of its effect on economic growth; thus social welfare more broadly defined can be affected by this sector's business model for funding research and development, a model that relies on the incentive value of patent rights to produce adequate profits.<sup>8</sup>

In these specific circumstances, social welfare analysis should take into account both the profit-as-incentive claims of pharma and biotech patent holders, and the human rights claims of under-supplied populations because social welfare is advanced both by encouraging patent-seeking research and by supplying life-sustaining needs, because social welfare calls for both sufficiently high profits to patent holders and sufficiently low prices to satisfy demand in the least-developed countries. So it is that pharma and biotech patents present a special case insofar as they involve the supply of basic human needs. What is to be done in these circumstances to resolve what appears to be a true conflict?

In evaluating and addressing economic arguments for strong protection of patent and other IPRs, human rights activists might find useful several principles. First and foremost, TRIPS rules and practices founded on presumptions in favor of strong patent rights as a general matter can claim no economic foundation. In short, general claims about the economic necessity of patent protection cannot be sustained. Second and more specifically, patents as incentives for pharma and biotech research and development require not maximizing profits but matching opportunity costs from competing investments. That is, lower profits can be high enough. One implication is that profitability analysis can proceed on a market-by-market basis. That is, monopoly profits from first world markets are typically sufficient to satisfy the sector's business model. Hence lower prices in the least-developed economies would provide adequate benefits to patent holders, so long as they cover costs of supply and the price discrimination does not lead to widespread arbitrage by grey market imports

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<sup>8</sup> See, generally, Peritz, *An Essay. Taking Antitrust to Patent School: The Instance of Pay-for-Delay Settlements*, 58 ANTITRUST BULLETIN \_\_ (forthcoming, Spring 2013).

to developed countries. Third, in light of the preceding principles, one size need not fit all. Policy analysis can put differentiated patent protection into play: Patent terms for life-saving medications need not extend a full 20 years, though full terms might be appropriate for lifestyle drugs whose intended consumers populate first world markets; such differentiation in patent rights would permit generic life-saving drugs earlier market entry in less developed countries. Fourth, local production and distribution should be part of the policy solution, along with the necessary technology transfer and export controls. Finally, strong biodiversity protection should be instituted, as it has been in Brazil, to include technology transfer and construction of local sites for research and development as well as production.

These principles can help channel public debate regarding trade and development policy in ways that permit the twenty-first century ensemble of human rights, including access to medicines, to serve as a pragmatic ethic to influence the scope and substance of patent protection that provides adequate incentive to spur research and development of life-saving drugs in the pharma and biotech sector while taking into account those human rights served by their wider dissemination.

## RE-SHAPING THE TRIPS REGIME TO PROFIT HUMAN RIGHTS

The four chapters in the first part of the volume re-cast in new light recent deployments of human rights ethics and TRIPS obligations in developing countries and the BRIC group, while the six chapters in the second part put forward new proposals and recommendations for the use of human rights and related ethics to resolve conflict over IPRs in ways that can benefit less developed countries.

### **Part 1. Re-imagining Current Approaches**

In Chapter 1, Duncan Matthews demonstrates that non-governmental organizations (NGOs) have used human rights to “highlight the adverse impacts of IPRs on access to medicines to an extent far greater than previously thought.” Matthews describes how over the past decade, emphasizing the links between IP, access to medicines, and human rights has evolved into a key strategy for NGOs seeking to draw attention to the potentially adverse effects of patents for pharmaceutical products for public health, particularly for people living with Human Immunodeficiency Virus/Acquired Immune-Deficiency Syndrome (HIV/AIDS). The chapter describes how NGOs have not only reshaped the international debate

about the relationship between IPRs and access to medicines by framing it as a human rights issue, but have also utilized the concrete human rights principles enshrined in national constitutional laws as a practical tool in their campaigns, often to good effect. The chapter focuses on the NGO campaigns in South Africa, Brazil, and India.

In Chapter 2, Lifang Dong seeks to show the extent to which China respects its TRIPS obligations by contrasting its regime with those of its BRIC cohort. While “India, Brazil, and the Russian Federation still rely on domestic policy protection to evade the TRIPS Agreement,” in Dong’s view the absence of such domestic protections places “IP protection in China almost on a level with the regimes of developed countries.” Moreover, in arguing against the mainstream view that China’s IP regime is lax, Dong goes even further, seeking to show that “in some respects China’s level of IP protection has surpassed that of developed countries.” Within this context, the author recommends that, going forward, China should shape its IP protection in accord with the TRIPS provision permitting legislation to “protect public health and nutrition.”

In Chapter 3, Horacio Rangel-Ortiz finds virtue in recent bilateral patent and trademark agreements between the United States and Latin American nations, despite bilateralism’s poor reputation amongst trade and development policy makers who favor regional and global agreements. Arguing against the common wisdom, Rangel-Ortiz asserts that bilateralism can benefit less-developed countries, although they are “weak negotiators.” For one, “less developed countries can benefit from treaties that would not be attractive to their stronger counterparts” and, in consequence, would be rejected in a regional context. Second, bilateralism may eventually “lead to the international or regional uniformity or harmonization” that neither regional nor multilateral approaches have achieved. Moreover, the chapter shows that despite the stricter IP protection in the United States, bilateral agreements with Latin American countries have provided for protection of traditional knowledge and genetic resources as well as equitable sharing of benefits. Finally, the treaties have recognized the importance of taking measures necessary to protect public health under the terms of the Doha Declaration.

In Chapter 4, Charles R. McManis and Jorge Contreras seek to reframe understanding of the controversial Anti-Counterfeiting Trade Agreement (ACTA) in terms that reflect legitimate concerns of developing countries. Responding to broad criticism of the proposed agreement, McManis and Contreras tell another tale, a tale of developing countries, least-developed ones included among them, joining the ACTA negotiations on deepening concerns over “mounting empirical evidence that has linked trade in counterfeit and pirated goods with organized crime and terrorism” in the

Middle East, Latin America, East Africa, and Russia. The authors warn that these concerns should be separated from “the more controversial and quite distinct question of digital file sharing.” They conclude that “entanglement of the two issues in the ACTA negotiations serves as its own cautionary tale concerning the virtues of promoting a greater degree of transparency and public participation in these negotiations.”

## Part 2. Proposing New Approaches

In Chapter 5, Gustavo Ghidini focuses his analysis of TRIPS’ impact on least-developed countries (LDCs) by identifying two “normative profiles” that in his view support a double standard to their detriment. First, although the TRIPS provision allowing an additional ten years for compliance seems to reflect special dispensation, in fact developed countries have taken much longer than ten years to adopt strong IP laws, as have developing countries more recently. Second, the TRIPS provision allowing patent-granting countries to require *in situ* production harms LDCs by reducing opportunities for spillover of advanced technological knowledge and associated know-how. To ameliorate this double standard, Ghidini offers “redeeming reforms” of the two normative profiles. First, he introduces the idea that the uniform ten-year period should be replaced by individualized time schedules for compliance, based on the particular LDC’s level of development. Second, he proposes that a local working requirement would fit neatly under the TRIPS provision allowing “a limited exception to the exclusive rights” of the patentee, an exception less intrusive than the compulsory licensing or government use already permitted.

In Chapter 6, Molly Land examines the development impact of subjecting the international IP standards established by the TRIPS Agreement to the mandatory dispute resolution process of the WTO. There have been two important consequences for developing countries, in her view. First, countries have foregone flexibilities to which they would otherwise be entitled, concessions that have contributed to the regime’s “pro intellectual property climate.” Second, adjudicators have tended to give short shrift to the internal balancing properly associated with IP rights. The overly restrictive view of TRIPS flexibilities that has resulted has been particularly problematic for LDCs. To counter this loss of flexibilities, Land seeks to revive provisions available to developing and LDCs but currently disregarded in WTO dispute resolution.

In Chapter 7, Annette Kur and Marianne Levin report on a set of proposals to reform the TRIPS agreement, proposals developed at the Max-Planck-Institute for Intellectual Property, Competition and Tax Law in

Munich under the title 'Intellectual Property law in Transition' (IPT). IPT "set out . . . to explore ways to re-establish the balance between different interests involved, where that equilibrium may have been distorted by a one-sided, inflexible approach towards IP." IPT begins with a guarantee of "a minimum level of free or conditioned access for third parties to protected subject matter. . . . [and thus] to halt a potentially dangerous trend towards ever-stronger protection." The guarantee is founded on two basic principles: First, that "non-trade related values . . . such as public health and nutrition, are of seminal importance . . . in the sense of imposing a 'moral duty' on governments vis-à-vis their own population." Second, that "well-functioning, unimpeded competition figures as an objective of primary importance for the establishment and maintenance of a sound IP system." IPT's broadest intention is to recalibrate IP rights in ways that promote "sound and sustainable socio-economic development."

In Chapter 8, Linda Briceño Moraia proposes reforms for the TRIPS Agreement to accord with the Rio Convention on Diversity (CBD) in light of the Nagoya Protocol, though the protocol is not in force. In Moraia's view, such reforms would go a long way in "correcting the present imbalance of TRIPs," especially "the neglected interests of Developing Countries." The problem, as Moraia sees it, is to "guarantee the fulfillment of the objectives pursued by the CBD, without causing an undue burden to IP right holders." The main proposal calls for "reintroducing the local working requirement in the TRIPs Agreement, since it could have a 'teaching effect'" like that discussed in chapter five. Moreover, this chapter concludes, such a reform would serve the Doha Declaration's call for universal 'access to medicines' by unlocking the door to use of genetic resources.

In Chapter 9, James Odek offers ten policy recommendations to improve innovation in Kenya. These reforms are necessary "from the perspective of developing African countries, [because] the TRIPS Agreement is an illusion and a failed promise to spur technology transfer, creativity and innovation in developing and least developed countries." TRIPS has failed, in this view, because its principles "have no local, cultural or legal roots." Moreover, TRIPS is "tilted towards appropriation of knowledge rather than transfer and diffusion of technology." As a result, "ideational power . . . is weak among developing and least developed countries." Odek's policy recommendations stress the importance of recognizing the interests of LDCs, despite TRIPS pressures to the contrary, and the necessity of political will to implement them. The chapter concludes with sixteen specific recommendations "to improve Kenya's creative and innovative capacity."

In the concluding chapter, Marco Ricolfi analyzes the importance of public sector information (PSI) to both developed and developing countries.

In his view, the critical importance of PSI stems from the new paradigm for innovation that has emerged in the past two decades: Innovation is no longer individual- or organization-based, but rather network-driven. These digital networks face the twin problems of data validity and reliability, and data access. In the absence of a uniform approach, there have developed few solutions, most notably the free access approach within the United States, and the European Union directives on data base and data privacy protection. Ricolfi observes that “developing countries have a totally free hand in determining the IP status of data which are candidates to become PSI.” In this light, he assesses the costs and benefits of adopting the United States and European Union approaches, then concludes with two recommendations for developing countries regarding the process of digitization and the importance of selecting “machine readable formats.”